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FDA Knows DNA Fragments in Vaccines Poses Health Risks — So Why Isn't It Concerned About mRNA COVID Shots?

The U.S. Food and Drug Administration acknowledges the possibility that fragments of DNA left over by the vaccine manufacturing process can be incorporated into a patient's own DNA, to potentially cause cancer, yet the agency maintains it "stands behind its findings of quality, safety, and efficacy for the mRNA vaccines."

By Maryanne Demasi, Ph.D.

11

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The recent findings of DNA fragments in the Pfizer and Moderna COVID-19 vaccines have led many to question why the U.S. Food and Drug Administration (FDA), which is responsible for monitoring the quality and safety of the vaccines, has failed to sound the alarm.

For years, the FDA has known about the risk posed by residual DNA in vaccines. Its own guidance to the industry states:

> "Residual DNA might be a risk to your final product because of oncogenic and/or infectivity potential. There are several potential mechanisms by which residual DNA could be oncogenic, including the integration and expression of encoded oncogenes or insertional mutagenesis following DNA integration."

Put simply, the FDA acknowledges the possibility that fragments of DNA left over by the manufacturing process can be incorporated into a patient's own

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DNA, to potentially cause cancer.

The FDA and the World Health Organization (WHO) guidelines consider the amount of residual DNA in a single dose of traditional vaccine should not exceed 10 ng (one billionth of a gram).

But this limit — used for traditional vaccines — is unlikely to be relevant to the mRNA vaccines whose lipid nanoparticles can penetrate inside cells to deliver the mRNA efficiently.

A recent preprint paper by Speicher et al. analyzed batches of the monovalent and bivalent mRNA vaccines in Canada.

The authors found "the presence of billions to hundreds of billions of DNA molecules per dose in these vaccines. Using fluorometry all vaccines exceed the guidelines for residual DNA set by FDA and WHO of 10 ng/dose."

Speicher et al. also reported finding fragments of DNA larger than 200 base pairs (a measure of the length of the DNA) which also exceeds FDA guidelines.

Notably, the authors commented that for the Pfizer product, the higher the level of DNA fragments found in the vaccine, the higher the rate of serious adverse events.

Some experts say the risk of genome integration in humans is very low, but a recent publication in Nature found that around 7% of cells are integrated when mixed with a transfection solution containing linear pieces of DNA.

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Is the FDA concerned?

The FDA continues to insist that any residual DNA contamination in the COVID-19 vaccines is not a problem and that it "stands behind its findings of quality, safety, and efficacy for the mRNA vaccines."

"While concerns have been raised previously as theoretical issues, available scientific evidence supports the conclusion that the minute amounts of residual DNA do not cause cancer, or changes to a person's genetic code," added the FDA.

The FDA would not provide the "available scientific evidence" to support its claim, but it's worth noting that the vaccines' own product labels show that genotoxicity and carcinogenicity tests were not carried out prior to their use.

David Wiseman, a research bioscientist involved in medical product development and co-author on the study by Speicher et al. said the FDA's claim that there is no evidence of a cancer link is becoming "untenable."

"The CDC's [Centers for Disease Control and Prevention] own analysis on the vaccine's safety signal in VAERS [Vaccine Adverse Event Reporting System] shows there could be a signal for some cancers," said Wiseman pointing to a report he co-authored and sent to the National Academies.

In the table (highlighted in yellow), a safety signal is considered to be significant, and worthy of further investigation, if the value in the column marked PRR exceeds 2 and the value in the Chi-Square column exceeds 4.

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The FDA would not confirm if it found levels of DNA that exceeded acceptable levels, nor if it was investigating further.

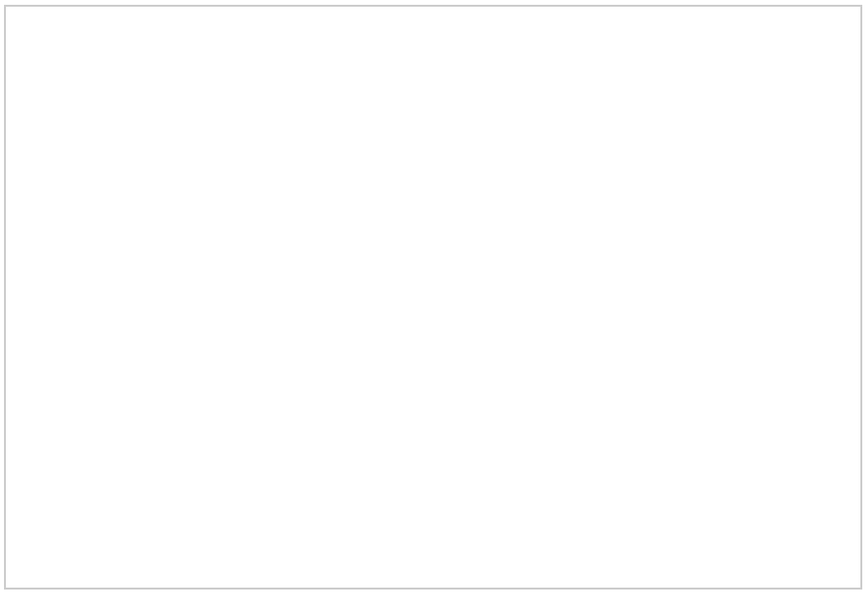
Instead, after months of inquiries, the FDA sent boilerplate responses to me (and other media) saying, "With over a billion doses of the mRNA vaccines administered, no safety concerns related to residual DNA have been identified."

In response to a list of questions about its testing and oversight, the FDA said it "does not have any additional information to provide at this time."

Poor manufacturing oversight

We now know that Pfizer's vaccine used in clinical trials (Process 1) was manufactured differently from the vaccine that was injected into the wider population (Process 2).

This switch from Process 1 to Process 2 is what introduced the plasmid DNA impurities (see red circles), which could change the safety profile of the vaccine.



I asked the FDA if it had any human data on the comparison of the two processes.

The agency pointed me to the FDA's emergency use authorization (EUA) review memo dated Nov. 20, 2020, which suggested that the testing was "ongoing."

The three-year-old document stated that "A more comprehensive comparability assessment encompassing additional lots from multiple DP [drug product] manufacturing nodes is ongoing and the results will be provided to the EUA upon completion of the study."

When I asked the FDA for access to the "ongoing" results, I was instructed to obtain the information from Pfizer, but the drug company did not respond to my inquiries.

A Freedom of Information (FOI) request by Nick Hunt of the Daily Sceptic may explain why.

Pfizer promised the regulator that it would compare the safety and immunogenicity of the two processes in participants and report back by February 2021, but it seems those studies were never done.

The FOI stated:

> "In October 2020 an exploratory objective was added in the C4591001 study to describe safety and immunogenicity of vaccines produced by manufacturing 'Process' or 'Process 2' in participants 16 to 55 years of age.
>
> "This exploratory objective was removed and documented in protocol amendment 20 in September 2022 due to the extensive usage of vaccines manufactured via 'Process 2'. Thus, this process comparison was not conducted as part of the formal documentation within the protocol amendment."

Wiseman said, "Given the magnitude of the process change, from my experience in medical product development, these sorts of biological comparability studies would certainly have been expected to be undertaken by Pfizer."

He added, "The fact that Pfizer was given a free pass indicates a significant lapse in regulatory oversight."

Kevin McKernan, the genomics expert who made the discovery of DNA fragments in the vaccines earlier this year, says there's "no incentive" now for Pfizer to carry out this comparative testing.

"It's speculation on my part, but I suspect they might've seen increased adverse events with the commercial batch and buried the data knowing the train had left the station at that point," said McKernan.

"There was no political will to stop vaccinating, and Pfizer probably knew the regulators would let them get away with not testing the commercial batches for the population," he added.

Originally published by Brownstone Institute.

The views and opinions expressed in this article are those of the authors and do not necessarily reflect the views of Children's Health Defense.

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Maryanne Demasi, Ph.D. is an investigative medical reporter, speaker and TV presenter/producer.

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Best Newest Oldest

el Gallinazo
2 days ago

"So Why Isn't It Concerned About mRNA COVID Shots?"

As Katherine Watt and Sasha Latypova have ably documented, the FDA is not concerned for two reasons. First, the US DoD purchased the fake vaccines only as vague "countermeasures" and with no specifications, so the FDA (or the CDC as well) had no real jurisdiction over them. They just pretended to as a form of kabuki theater to fool the public. Second, the fake vaccines were in reality deliberate bioweapons, designed by the US DoD and directed at the 99.9% so the FDA was also not concerned because they were just doing what they were designed to do, i.e. kill and maim people.

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Polly Green → el Gallinazo
2 days ago

Exactly right. They're not concerned about DNA fragments because they're not concerned about us.

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GarySummers → Polly Green
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"Agenda to Depopulate the Planet Through COVID Vaccination. Revealed by Government Reports and Pfizer Documents"

The push for mass Covid-19 vaccination was never about combating a virus. It was about reducing the global population.

This goal aligns with the interests of certain powerful corporations and individuals who stand to benefit from a smaller, more manageable population now that AI is advanced enough to replace hundreds of millions of workers.
https://www.globalresearch....

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Will anyone ever be held Accountable?

"DNA Contamination In COVID-19 Vaccines May Explain Rise In "Cancers", "Clots", "Autoimmune Diseases": Pathologist"
'Recently, researchers found that vaccine vials containing Pfizer's COVID-19 vaccines had billions of residual DNA fragments, including molecules derived from Simian Virus 40 (SV40) used as "promoters" or "enhancers" that help produce the mRNA molecules that help human cells make proteins that trigger an immune response inside the body.'
https://www.zerohedge.com/m...

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JoJo
2 days ago

An Op-ed has been posted on Trial Site News titled "Musculoskeletal Disorders Post-COVID-19 Vaccinations" (https://www.trialsitenews.c.... It documents the wider scope of musculoskeletal and connective tissue disorder symptoms that appeared in VAERS (Vaccine Adverse Events Reporting System) following COVID-19 vaccinations, and addresses post-Influenza vaccination musculoskeletal and connective tissue disorders as well. These types of disorders do not receive the attention that the more well-known cardiac disorders and cancers do, but they are quite prevalent, as the results show.

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Rob DF
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This entire vaccine rollout is a dark comedy of the highest degree. Another problem discover? Just add it to the pile....

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LinUK
2 days ago

So they've gone from "trust us there is **NO** DNA in the jabs". To "well, ok there is DNA in the jabs, but it's not going to do you any harm".

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Diane Chase
2 days ago

In other words "Don't Look Up"

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Clare Goldsberry
a day ago

This whole thing from the time of the patents on the SARS-CoV-2 virus through to the deadly vaccine, was a planned depopulation venture. Fretting over the unsustainable population numbers (now at 8 billion) was designed to do exactly what it was intended to do. This experiment proved very valuable to achieving the intended outcome: Kill people with a virus that was sold as a "vaccine" to prevent illness and death, but do it in such a way that it appeared that people were dying of heart attacks, strokes and various forms of cancer -- all natural deaths, of course, resulting from the destruction of the immune system. Simple. Easy, No regrets.

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brbg
5 hours ago

The pharmaceutical companies are guilty of genocide.

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Gary Brown
21 hours ago

The medical establishment knows when we know.

September 19, 2014 Autism And Cancer Related To Human Fetal DNA In Vaccines Study

New Study In Journal Of Public Health

http://www.globalresearch.c...

AUGUST 21, 2020 Autism—The Most Glaring Aspect of the Deterioration of Health Among Our Kids?

The numbers: We've watched the numbers explode with no end in sight. Over the last 20 years the Centers for Disease Control and Prevention have routinely updated the autism rate: 2001: one in 250
2004: one in 166
2007: one in 150

Children's Health Defense

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